Exhibit A

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

3M Company et al.,

Petitioners,

v.

Scott Augustine et al.,

Respondents.

Civil No. 15-mc-64 (JNE/FLN)
Civil No. 15-mc-65 (JNE/FLN)

ORDER

Lori G. Cohen and Jerry W. Blackwell for Petitioners.
James Randall Benham for Respondents.[1]

THIS MATTER came before the undersigned United States Magistrate Judge on October 26, 2015 on Petitioner 3M Company's motion to compel discovery (ECF No. 1, Case No. 15-mc-64; ECF No. 1, Case No. 15-mc-65) and Respondent Scott Augustine's motion for protective order (ECF No. 27, Case No. 15-mc-64; ECF No. 25, Case No. 15-mc-65). For the reasons set forth below, the Petitioners' motions are **GRANTED in part and DENIED in part** and Respondents' motions are **DENIED**. Additionally, Petitioner's motions for leave to file reply/surreply (ECF No. 40, Case No. 15-mc-64; ECF No. 38, Case No. 15-mc-65) are **DENIED**.[2]

I. FACTUAL BACKGROUND

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[1] Ben W. Gordon, Genevieve M. Zimmerman, David W. Hodges, and Gabriel Assaad, Counsel for Plaintiffs' Tommy Walton and Timothy Johnson, were also present at the hearing on October 26, 2015.

[2] The discovery dispute presented in Case No. 15-mc-64 (JNE/FLN) and Case No. 15-mc-65 (JNE/FLN) are identical. The Court will therefore cite only to CM/ECF docket entries in Case No. 15-mc-64 (JNE/FLN).The Court's analysis and findings of fact and law, however, apply to both cases equally.

The cases underlying the present discovery dispute are products liability actions pending in Districts outside of Minnesota: *Timothy Johnson v. 3M Company et al.*, No. 2-14-cv-02044 (D. Kan.) ("*Johnson*"), and *Tommy Walton v. 3M Company et al.*, No. 4:13-cv-01164 (S.D. Tex.) ("*Walton*"). Both cases involve allegations surrounding the Bair Hugger FAW ("Bair Hugger"), which was invented by Dr. Scott Augustine. ECF No. 1. In both *Johnson* and *Walton*, 3M served nearly identical subpoenas, seeking to depose Dr. Augustine as well as documents related to fifteen discovery requests. Pet'rs' Ex. D, ECF No. 4. Dr. Augustine is located in the State of Minnesota.

3M, by email on August 18, 2015, requested that Dr. Augustine commit to provide responses to the fifteen document requests, or to provide a privilege log, by August 25, 2015. ECF No. 4, Ex. N. When Augustine did not respond to the email, 3M filed the present motion to compel on August 21, 2015. ECF No. 1. Subsequent to the filing of this motion, Dr. Augustine provided responses to much of 3M's requested discovery on August 25 and 26, 2015. *See* Mem. in Opp'n 2, ECF No. 25. However, of the fifteen original requests, there are seven document requests that are still in dispute:

1. Any and all documents, transcripts, medical records, court filings, discovery, or other documents from the [*Johnson* and *Walton* lawsuits], that you have received or reviewed.

2. Any and all documents constituting, relating or referring to any communications, meetings, interactions, services or payments exchanged, or agreements between (a) You, Augustine Biomedical, or any other person or entity acting on Your behalf; and (b) the law firms Kennedy Hodges, LLP and/or Farrar & Ball, LLP, including but not limited to calendar entries, invoices, emails, letters, documents exchanged, and meeting notes.

10. Any and all documents, including correspondence and draft correspondence, related to the MedWatch report referenced in Your July 9, 2010, letter to Kurt Hilzinger, Court Square Capital Partners.

11. Any and all documents, data, photographs, or video relating to the production of any videos posted to http://heat-rises.blogspot.com that claim to show disruption of operating room airflow by forced-air warming, including footage taken but not posted online, documentation regarding the test protocols, documentation regarding

all aspects of the ventilation system of the operating room and its performance, and documentation regarding the forced air warming blower and blankets used and any adjustments made to the devices.

12. Any and all social media postings, messages, and blog entries, posted by You, Augustine Biomedical, or any other person or entity acting on Your behalf that reference or relate to forced-air warming or to the [*Johnson* and *Walton* lawsuits], from January 1, 2013, to today.

13. Any and all electronic or paper files and file folders related to the [*Johnson* and *Walton* lawsuits]

14. Any and all documents reviewed by you in preparation for this deposition

ECF No. 4, Ex. D at 5. Augustine has raised several objections to 3M's enumerated requests.

As to the dates for Dr. Augustine's depositions, counsel have agreed that he will be deposed on October 13, 2015 and October 15, 2015, one day for each respective case. ECF No. 1 at 8. However, on October 1, 2015, Augustine filed a motion for a protective order (ECF No. 27) requesting that all document requests and his depositions in the underlying cases be stayed pending an MDL determination on December 3, 2015. Additionally, Augustine argues that, at least with regards to Request No. 12, the subpoena is unduly burdensome and constitutes harassment and therefore a protective order is appropriate. ECF No. 27 at 6–7. However, as 3M articulated in its motion papers and at the hearing, this Court has no control over the discovery schedule set by the courts in Kansas and in Texas. ECF No. 33 at 1–2. As the Court understands the schedules in each of those cases, fact discovery closes in *Johnson* on December 31, 2015, and all discovery must be completed in *Walton* by February 29, 2016. ECF No. 1 at 7, Case No. 15-mc-65; Zimmerman Letter Ex. 1, ECF No. 43. In each case, the court has denied 3M's request to stay proceedings pending a ruling by the JPML regarding whether to consolidate cases in a single district. *See* ECF No. 43, Ex. 1. Additionally at the hearing, 3M's counsel represented that much of the material and questions that would be asked at the deposition of each case would overlap but that nevertheless, 3M requests two

full days to depose Augustine.

II. LEGAL STANDARD

"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense . . . ." Fed. R. Civ. P. 26(b)(1). However, Rule 26(c)(1) of the Federal Rules of Civil Procedure states that a "court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." "The burden is therefore upon the movant to show the necessity of [a protective order's] issuance, which contemplates a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements." *Gen. Dynamics Corp. v. Selb Mfg. Co.*, 481 F.2d 1204, 1212 (8th Cir. 1973). A party seeking to prevent a deposition, however, "carries a heavy burden to show why discovery should be denied." *Bombardier Recreational Prods.*, 2014 WL 5685462, at *3 (quoting *Apple Inc. v. Samsung Elecs. Co.*, 282 F.R.D. 259, 263 (N.D. Cal. 2012)).

III. CONCLUSIONS OF LAW

A. Augustine's Motion for Protective Order

The Court denies Augustine's motions for a protective order and request to stay production of document requests or his deposition pending the MDL determination. The Court has no control over the discovery schedules set in the underlying cases and it would be unfair to deprive 3M of discovery. ECF No. 33 at 1–2. Furthermore, it is mere speculation at this point whether *Walton* and *Johnson* would be included in an MDL consolidation or that the MDL consolidation would be granted. Indeed, 3M represented at the hearing that it is opposing the MDL consolidation. As discovery is closing in both *Walton* and *Johnson*, discovery should go forward pursuant to the schedules set by each respective court. Accordingly, Augustine's motions for a protective order (ECF No. 27, Case No. 15-mc-64; ECF No. 25, Case No. 15-mc-65) are denied.

B. Document Requests

1. Request Nos. 1, 2, and 13

Augustine objects to Request Nos. 1, 2, and 13, on the grounds that the responsive documents are protected by attorney-client privilege. ECF No. 25 at 2–6 (cited incorrectly by Respondents as Nos. 1 and 12). Augustine further states that he need not provide a privilege log for those responsive documents protected by privilege because the *Walton* court has held that Kennedy Hodges, LLP did not need to provide a privilege log concerning communications between Tommy Walton and its firm. *Id.* at 5–6. However, as 3M points out, the *Walton* court specifically held that 3M may seek this discovery directly from Augustine. Ex. A, ECF No. 37. To date, Augustine has not provided a privilege log describing each document being withheld as well as a description of the privilege asserted as it pertains to that document. Rather, Augustine has simply asserted a blanket privilege over all the requested documents and relies on the *Walton* court's order that the law firms' communications with plaintiff did not have to be provided in a privilege log. *Id.* However, the *Walton* court's holding did not apply to him, and it specifically advised 3M that it may seek discovery directly from Augustine. ECF No. 37, Ex. A. Furthermore, "blanket assertions of the privilege are not favored." *In re Martenson*, 779 F.2d 461, 463 (8th Cir. 1985). "[T]he privilege is not a general one. It must be asserted as to particular questions." *Id.* Accordingly, the Court concludes that Augustine cannot assert blanket privilege to discovery requests Nos. 1, 2, and 13. 3M is entitled to the information it has requested. Augustine must either provide this information or provide a detailed privilege log describing each document being withheld as well as a description of the privilege asserted as it pertains to that document.

2. Request No. 10

As to Request No. 10, which seeks all documents related to the MedWatch report referenced

in a letter Augustine wrote to Kurt Hilzinger dated July 9, 2010, Dr. Augustine asserts that he has no knowledge of this letter whatsoever. ECF No. 25 at 2 (cited incorrectly by Respondents as No. 9). 3M has agreed to provide Augustine with the letter in order to clarify its Request No. 10. After Augustine receives clarification of the requested MedWatch reports referenced in the letter, Augustine must provide the information requested in Request No. 10. To the extent that Augustine believes that any of the requested material is privileged, Augustine must provide a detailed privilege log as explained above.

3. Request No. 11

Augustine asserts that he has already turned over all responsive documents to Request No. 11. ECF No. 25 in at 2 (cited incorrectly by Respondents as No. 10). 3M contests Augustine's claim that all responsive documents to Request No. 11 have been turned over and specifically seeks the following: all the videos requested, any still photographs from the actual operating room testing that appears in the video on Augustine's website, any testing protocols for either the simulated or the actual operating room demonstration/study, all information or documentation regarding the ventilation system of the constructed operating room and its performance (i.e., the speed of the laminar supply diffuser used with the vents), documentation regarding the draping and blankets used, any information about the ventilation of the actual operating room as seen on the video, information or documentation regarding the blower and blankets used and any adjustments made to the devices, information about the materials used in the study (i.e., particles but not limited to a photo of the particle/bubble emitter), the final and draft scripts of the voice-overs of the studies posted on Augustine's website, and information related to the production and editing of the videos (i.e., alterations in speed of certain portions). ECF No. 36 at 3–4.

Because Augustine has not made any objection to Request No. 11, any outstanding responsive

documents to Request No. 11 that have not yet been turned over must be provided to 3M. To the extent that Augustine believes that any of the requested material is privileged, Augustine must provide a detailed privilege log as described above.

4. Request No. 12

Augustine also objects to Request No. 12 in that requesting all social media postings, messages, and blog entries from January 1, 2013 to present that reference or refer to forced air warming or the underlying lawsuits is overly burdensome. ECF No. 25 at 2–3 (cited incorrectly by Respondents as No. 11). 3M responds that because Augustine's theories and studies form the basis of Plaintiffs' underlying claims and alternative design theories, this information is relevant. ECF No. 36 at 5–6. Furthermore, 3M seeks Augustine's own public postings from the past two years and asserts that Augustine is uniquely in control of the information requested and the time frame is limited. *Id.*

Augustine has requested either a protective order or asks that 3M narrow its discovery request for Request No. 12. ECF No. 25 at 3–4. However, the Court agrees with 3M that it is merely seeking material Augustine disseminated publicly over the past few years that reference either the underlying lawsuits or Augustine's belief in a safer alternative design to the Bair Hugger. It is clear to the Court that this information relates to what will undoubtedly be a key issue in both disputes. The Court concludes that the requested materials' relevance outweighs the burden it places on Augustine to turn over materials uniquely in his possession that he has made public over the past few years. Furthermore, the Court does not find this request to constitute harassment of Augustine given that it is highly relevant to the issues presented in the underlying cases. Accordingly, Augustine's motion for protective order and his request to narrow Request No. 12 is denied. 3M is entitled to responsive documents for its discovery Request No. 12.

5. Request No. 14

Augustine's counsel represented at the hearing that Dr. Augustine has not, and will not, review any documents in preparation for any deposition, as 3M requested in Request No. 14. Accordingly, the Court concludes that 3M's Request No. 14 is moot.

B. Deposition of Dr. Augustine

Because the Court denies Augustine's motion for protective order to the extent that he seeks a stay pending the MDL determination, the Court concludes that 3M may depose Augustine pursuant to the Federal Rules of Civil Procedure. However, the Court may limit discovery if it "is unduly burdensome or expensive, taking into account the needs of the case." Fed. R. Civ. P. 26(g)(B)(iii). 3M represented at the hearing that much of the questions and material it seeks to depose Augustine on in both *Walton* and *Johnson* overlap and relate mainly to the Bair Hugger and Augustine's theories for a safer design alternative. Accordingly, the Court concludes that 3M is limited to its deposition of Augustine for one day of seven hours. Fed. R. Civ. P. 30(d)(1). Augustine must make himself available for deposition forthwith as specified in 3M's deposition notices and subpoenas subject to the Court's limitation.

IV. ORDER

Based on the foregoing, and all of the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Petitioner's motions to compel (ECF No. 1, Case No. 15-mc-64; ECF No. 1, Case No. 15-mc-65) are **GRANTED in part DENIED in part** as follows:

    a. 3M's motion to compel deposition of Dr. Augustine is **GRANTED** to the extent that 3M may depose Dr. Scott Augustine for one day, totaling seven hours, pursuant to the Federal Rules of Civil Procedure. In all other respects, the motion to compel deposition of Dr. Augustine is **DENIED**.

    b. To the extent 3M seeks responsive documents for Request Nos. 1, 2, 11–13,

the motion is **GRANTED**. If Augustine believes a responsive document is privileged, he must include such document on a privilege log that describes the document as well as the privilege asserted pursuant to Federal Rules of Civil Procedure 26(b)(5).

c. To the extent 3M seeks responsive documents for Request No. 10, the motion is **GRANTED**. 3M must provide Augustine with the letter Augustine wrote to Kurt Hilzinger dated July 9, 2010, to clarify its request. Augustine must then produce responsive documents for Request No. 10. If Augustine believes a responsive document is privileged, he must include such document on a privilege log that describes the document as well as the privilege asserted pursuant to Federal Rules of Civil Procedure 26(b)(5).

d. To the extent 3M seeks responsive documents pursuant to Request No. 14, the motion is **DENIED as moot**.

e. To the extent 3M requests its costs and attorney's fees, the motion is **DENIED**.

2. Petitioner's motions for leave to file reply/surreply (ECF No. 40, Case No.15-mc-64; ECF No. 38 Case No. 15-mc-65) are **DENIED**.

3. Scott Augustine's motions for protective order (ECF No. 27, Case No. 15-mc-64; ECF No. 25 Case No. 15-mc-65) are **DENIED**.

DATED: November 3, 2015

s/Franklin L. Noel
FRANKLIN L. NOEL
United States Magistrate Judge

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, vs. JAMES RANDALL BENHAM, Defendant.	)	CRIMINAL NO. CR 03-321 ADM/AJB

STIPULATION OF FACTS

The United States of America, by and through its attorneys, Ronald J. Tenpas, United States Attorney for the Southern District of Illinois, Michael J. Quinley, Assistant United States Attorney for the Southern District of Illinois, and Rina C. Tucker, Trial Attorney, United States Department of Justice, along with Defendant James Randall Benham by and through his attorneys, William J. Mauzy and Amos Cohen hereby enter into this Stipulation of Facts, agreeing that at all times relevant to the Plea Agreement agreed upon by the above-referenced parties that:

1. The Defendant was General Counsel of Augustine Medical, Inc. ("AMI"), a Minnesota corporation that manufactured and sold Warm-Up Active Wound Therapy ("Warm-Up").

2. The Defendant knew that claims for Warm Up were periodically submitted by others for reimbursement to the Medicare program, a Federal health care program.

3. On or about June 27, 2000, Defendant Scott D. Augustine received a letter from TriSpan Health Services, a fiscal intermediary of the Medicare program which had earlier approved coverage for

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Warm Up. TriSpan had now determined that Warm Up was investigational. Defendant believed that this determination was material.

4. Shortly thereafter, the Defendant knowingly and intentionally aided and abetted others in deciding not to disclose the June 27th letter to Southern Medical Distributors.

5. By entering into this Stipulation of Facts, the Defendant admits that the facts set forth herein establish that he knowingly and intentionally aided and abetted the offense 42 U.S.C. Section 1320a-7b(a)(2) as set forth in an Information filed herewith and is in fact guilty of that offense.

SO STIPULATED,

JAMES RANDALL BENHAM

WILLIAM J. MAUZY
AMOS COHEN,
Attorneys for Defendant

Date: 6/29/04

RONALD J. TENPAS
United States Attorney,
Southern District of Illinois

MICHAEL J. QUINLEY
Assistant United States Attorney,
Southern District of Illinois;
Special Assistant United States Attorney,
District of Minnesota

RINA C. TUCKER
Trial Attorney, U.S. Department of Justice

Date: June 29, 2004

Exhibit B-1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	CRIMINAL NO. CR 03-321 ADM/AJB
	)	(6)
SCOTT D. AUGUSTINE,	)	
	)	
Defendant.	)	
	)	

STIPULATION OF FACTS

The United States of America, by and through its attorneys, Ronald J. Tenpas, United States Attorney for the Southern District of Illinois, Michael J. Quinley, Assistant United States Attorney for the Southern District of Illinois, and Rina C. Tucker, Trial Attorney, United States Department of Justice, along with Defendant Scott D. Augustine by and through his attorneys, John W. Lundquist and Dulce Foster hereby enter into this Stipulation of Facts, agreeing that at all times relevant to the Plea Agreement agreed upon by the above-referenced parties that:

1. The Defendant was CEO of Augustine Medical, Inc. ("AMI"), a Minnesota corporation that manufactured and sold Warm-Up Active Wound Therapy ("Warm-Up").

2. The Defendant knew that claims for Warm Up were periodically submitted by others for reimbursement to the Medicare program, a Federal health care program.

3. On or about June 27, 2000, Defendant Scott D. Augustine received a letter from TriSpan Health Services, a fiscal intermediary of the Medicare program which had earlier approved coverage for

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Warm Up. TriSpan had now determined that Warm Up was investigational.. Defendant believed that this determination was material.

4. Shortly thereafter, the Defendant knowingly and intentionally aided and abetted others in deciding not to disclose the June 27th letter to Southern Medical Distributors.

5. By entering into this Stipulation of Facts, the Defendant admits that the facts set forth herein establish that he knowingly and intentionally aided and abetted the offense 42 U.S.C. Section 1320a-7b(a)(2) as set forth in an Information filed herewith and is in fact guilty of that offense.

SO STIPULATED,

RONALD J. TENPAS
United States Attorney,
Southern District of Illinois

SCOTT D. AUGUSTINE

MICHAEL J. QUINLEY
Assistant United States Attorney,
Southern District of Illinois;
Special Assistant United States Attorney,
District of Minnesota

JOHN W. LUNDQUIST
DULCE FOSTER,
Attorneys for Defendant

RINA C. TUCKER
Trial Attorney, U.S. Department of Justice

Date: 6/29/04

Date: June 29, 2004

Exhibit C

CASE | DECISION | JUDGE | FOOTNOTES

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF

SUBJECT:

Scott D. Augustine,

DATE: February 03, 2006

Petitioner,

- v -

The Inspector General.

Docket No.**C-05-374**
Decision No. **CR1406**

DECISION

...TO TOP

DECISION

I sustain the determination of the Inspector General (I.G.) to exclude Petitioner, Scott D. Augustine from participating in Medicare, Medicaid, and all federal health care programs for a period of five years. I find thatthe I.G. is authorized to exclude Petitioner pursuant to Section 1128(a)(1) of the Social Security Act (Act), and the five-year exclusion imposed by the I.G. is the minimum mandatory period of exclusion under the Act. Act, section 1128(a)(1).

I. BACKGROUND

Scott D. Augustine (Petitioner) was the founder and Chief Executive Officer of Augustine Medical, Inc. (AMI). AMI manufactured and sold Warm-up Active Wound Therapy, a wound care therapy system. TriSpan Health Services (TriSpan), a Medicare fiscal intermediary, paid for Warm-up Active Wound Therapy under the Medicare guidelines. On or about June 27, 2000, Petitioner received a letter from TriSpan (June 27th TriSpan letter) indicating that Warm-up was considered "investigational." The June 27th TriSpan letter was not disclosed to Southern Medical Distributors (SMD), a durable medical equipment (DME) distributor set up as part of a government sting operation. P. Response at 2; I.G. Exhibit (Ex.) 5.

Petitioner was prosecuted by the United States and charged with knowingly and willfully aiding and abetting others in causing to be withheld from Southern Medical Distributors a material fact for use in determining rights to benefits and payments under a Federal health care program, that being the Medicare program, in violation of 42 U.S.C. § 1320a-7b(a)(2) and 18 U.S.C. § 2. Petitioner pleaded guilty to that

charge. I.G. Exs. 3, 4. As part of the misdemeanor plea, Petitioner signed a stipulation of facts in which he agreed that TriSpan's determination, that Warm-Up was investigational, was material and that he knowingly and intentionally aided and abetted the offense. Petitioner was sentenced, on September 15, 2004, to a three-year period of probation, fined $2,000,000, and ordered to pay a special assessment of $25. I.G. Ex. 2.

The I.G. notified Petitioner by letter dated March 31, 2005 of his exclusion from participation in Medicare, Medicaid, and all federal health care programs for a mandatory five-year period pursuant to section 1128(a)(1) of the Act. The I.G. further advised Petitioner that the action taken was based upon Petitioner's conviction in the United States District Court for the District of Minnesota, of a criminal offense related to the delivery of an item or service under the Medicare program. I.G. Ex. 1; P. Ex. 4, at 4.

By letter dated May 31, 2005, Petitioner timely filed a request for review of the I.G.'s exclusion. In his request for hearing, Petitioner maintained that the I.G. erred in excluding him under the provisions of section 1128(a)(1) of the Act and, instead, should have exercised his discretion and excluded Petitioner under section 1128(b)(11). On July 20, 2005, I convened a telephone conference with counsel for the I.G. and Petitioner in this matter.[(1)]

During that conference call, I informed the parties that my jurisdiction was limited in this case to a determination as to whether the I.G. had the legal authority to exclude Petitioner and whether the period of exclusion was reasonable. Petitioner reiterated the argument set forth in his hearing request. With the concurrence of the parties, during the conference call, I established a briefing schedule for the parties to address Petitioner's argument as to whether an ALJ has the authority to determine if an exclusion should be implemented pursuant to the "mandatory" provision of the Act (section 1128(a)) as opposed to a "permissive" exclusion under section 1128(b) of the Act.

Thereafter, on August 19, 2005, the I.G. submitted an initial brief (I.G. Br.). Accompanying the brief, the I.G. filed five proposed exhibits (I.G. Exs. 1-5). In the initial brief, the I.G. argued the limited issue addressed during the prehearing conference and as outlined in my Order dated August 16, 2005. On September 22, 2005, Petitioner filed his response brief addressing the issues as discussed in the prehearing conference and as outlined in my Order memorializing the prehearing conference. (P. Response). Petitioner submitted four proposed exhibits (P. Exs. 1-4). However, as part of its response, Petitioner also argued that Petitioner's conviction did not affect the delivery of an item or service under a federal or state health care program and the case did not involve an overpayment by a federal or state health care program.

The I.G. filed a reply brief (I.G. Reply) on October 12, 2005, responding to the issues raised by Petitioner. The I.G. specifically argued that the I.G. had a legal basis to exclude Petitioner under section 1128(a)(1) and that Petitioner was convicted of an offense related to the delivery of items or service under Medicare.

Petitioner filed a motion for leave to file a sur-reply brief and sur-reply (P. Sur-Reply) on November 3, 2005. I granted Petitioner's motion for leave to file a sur-reply on November 28, 2005, and the sur-reply brief was accepted into the record. Neither party filed objections to the exhibits offered by the other party. I therefore admit I.G. Exs. 1-5 and P. Exs. 1-4 into evidence.

II. CONTROLLING STATUTES AND REGULATIONS

Section 1128(a)(1) of the Act requires the Secretary of Health and Human Services (Secretary) to exclude from participation in Medicare, Medicaid, and all other federal health care programs, any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under the Medicare or Medicaid programs. 42 U.S.C. § 1320a-7(a)(1).

An exclusion imposed under section 1128(a)(1) must be for a period of at least five years. Act, section 1128(c)(3)(B); 42 U.S.C. § 1320a-7(c)(3)(B). Pursuant to 42 C.F.R. § 1001.102(b), no exclusion pursuant to section 1128(a)(1) may be for less than five years.

An individual is "convicted" of a criminal offense within the meaning of section 1128 (i) of the Act -

> (1) when a judgment of conviction has been entered against the individual or entity by a Federal, State, or local court. . . .
>
> (2) when there has been a finding of guilt against the individual or entity by a Federal, State, or local court; [or]
>
> (3) when a plea of guilty or *nolo contendere* by the individual or entity has been accepted by a Federal, State, or local court. . . .

Act, section 1128(i); 42 U.S.C. § 1320a-7(i).

42 C.F.R. § 1001.2007(a)(1)(i) grants an ALJ the authority to address whether a legal basis for the imposition of an I.G. sanction exists.

III. FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Issue

The legal issue before me in this case is:

> •Whether there is a legal basis for the imposition of an exclusion under 1128(a) of the Act.

B. Findings and Discussion

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding in *italics* below as a separate heading. I discuss

each Finding in detail.

1. Summary disposition is appropriate in this case.

Summary disposition is appropriate where there are either no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts, or the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made. A party opposing summary disposition must allege facts which, if true, would refute the facts relied upon by the moving party. *See* Fed. R. Civ. P. 56(c).

Petitioner argues in its motion for leave to file a sur-reply that the purpose for the sur-reply was to correct a material factual error. Petitioner argues that failing to disclose the letter in issue in this case would not and could not have resulted in the delivery of items or services under Medicare because SMD was, in reality, part of the Government's sting operation and there was no chance that the Medicare program would pay for DME items provided by Petitioner. While Petitioner frames the issue as a material factual error, Petitioner is in reality making a legal argument that, because of the status of SMD as part of the Government sting operation, no claim could have been filed with the Medicare program. Therefore, according to Petitioner, Petitioner's conviction does not relate to an item or service under the Medicare program. The I.G. does not dispute that SMD was part of the Government's sting operation, nor does he dispute that no claim was submitted to Medicare in this case. Because I view Petitioner's argument as a legal rather than a factual issue requiring an in person hearing, I find the only issue that exists in this matter may be resolved as a question of law.

2. Petitioner was convicted within the meaning of section 1128(i) of the Act.

An exclusion under section 1128(a)(1) of the Act requires that two elements be shown: (1) that the individual or entity has been convicted of a criminal offense as defined at section 1128(i) of the Act; and (2) that the criminal offense be related to the delivery of an item or service under title XVIII or under any state health care program. The I.G. bears the burden of persuasion to prove, by a preponderance of the evidence, that both elements have been met. 42 C.F.R. §§ 1005.15(b)(1), (d).

The first element has been met. Petitioner does not dispute that, on June 29, 2004, he pleaded guilty to one count of a misdemeanor information which charged that he:

> . . . . knowingly and willfully aided and abetted others in causing to be withheld from SMD a material fact for use in determining rights to benefits and payments under a Federal health care program, that being the Medicare program, in violation of 42 U.S.C. § 1320a-7b(a)(2) and 18 U.S.C § 2.

P. Ex. 3, at 5; I.G. Ex. 3. A judgment of conviction was imposed on September 8, 2004, which sentenced Petitioner to three years probation, ordered to pay a fine in the amount of $2,000,000, and assessed a $25 special assessment. Petitioner

concedes that he was convicted within the meaning of section 1128(i) of the Act. *Id.* at 4. Therefore, I find that Petitioner was convicted within the meaning of section 1128(i) of the Act.

3. Petitioner's conviction was related to the delivery of service of an item or service under Medicare or a state health care program.

Petitioner asserts that there is no common sense connection or "nexus" between the criminal offense to which he pleaded guilty and an item or service under the Medicare program. First, Petitioner contends that the company to which the June 27th TriSpan letter allegedly should have been forwarded, SMD, was a corporate entity created by a governmental agency as party of a sting operation. P. Response at 2; P. Sur-Reply at 2. Petitioner suggests that, even if the June 27th TriSpan letter had been sent to SMD, there was no possibility of a delivery of an item or service, or a distribution of Medicare funds. Specifically, Petitioner asserts that "[SMD] never delivered the DME to any Medicare beneficiary. Because [SMD] was part of a government operation, there was no chance that the Medicare program would pay for the DME provided by AMI." P. Sur-Reply at 2. Petitioner continues by addressing the argument raised for the first time by the I.G. in its reply brief; that a nexus exists because "Petitioner's conviction involved acts that could have resulted in the delivery of items under Medicare." I.G. Reply at 5. If the I.G.'s argument is given any significant weight, Petitioner concludes, then Petitioner's exclusion under section 1128(a)(1) cannot be supported. Petitioner concludes that, based upon the I.G.'s contention, "it was impossible for the conduct underlying [Petitioner's] conviction to have resulted, directly or indirectly, in the delivery of an item under Medicare or the expenditure of Medicare funds. P. Sur-Reply at 2.

The I.G. asserts that Petitioner's conviction did "involve acts that could have resulted in the delivery of items under Medicare" even if no items were actually provided or claims filed. I.G. Reply at 5. Further, the I.G. contends that "[t]he possibility that others might submit claims to Medicare based on Petitioner's withholding of a material document provides the necessary nexus required by section 1128(a)(1) of the Act." *Id.*

Although Petitioner's argument raises an interesting question regarding the specific facts of this case, and the interpretation and application of what is *related to a delivery of an item or service under federal health care programs*, I am bound by the regulations and statutory provision which dictate this area of law.

The language which describes the relationship between an offense and an item or service in a health care program is spelled out in *Berton Siegel, D.O.*, DAB No. 1467 (1994). In *Siegel*, the Board determined that there had to be some nexus or common sense connection between the petitioner's offense and the delivery of an item or service under a covered program. The Board opined that:

> Congress could have simply required that a person be excluded when convicted of an offense related to Medicare or

> Medicaid. However, Congress instead required that a person be excluded when convicted of an offense related to the delivery of items or services under Medicare or Medicaid. Neither the ALJ nor the Board may fail to give effect to the plain meaning of the statute.

Id. at 5; *see also, Thelma Walley*, DAB No. 1367 (1992).

The Act does not define the term "nexus" with any degree of clarity. But, as was elucidated by ALJ Kessel in *Jeffrey Knute Connell*, DAB CR1271 (2005), "a crime that affects the performance of Medicare or a State Medicaid program - by affecting, either potentially or in fact, the quality of items or services that the program delivers, or the monies spent for the delivery of items or services - relates to the delivery of Medicare or Medicaid items or services." Based upon Judge Kessel's definition of the term "nexus," one with which I concur, it is clear that the facts in the instant case demonstrate a common sense connection (nexus) between the crime Petitioner pleaded guilty to and a delivery of item or service under Medicare. Petitioner concedes that he "pleaded guilty to a misdemeanor and accepted responsibility for aiding and abetting others in deciding not to forward the TriSpan letter to Southern Medical Distributors, a distributor of DME. . . ." P. Response at 2-3. However, Petitioner argues that in spite of his plea and conviction, it would have been virtually impossible for his failure to disclose the June 27th TriSpan letter to SMD to result in the delivery of an item or service under Medicare. P. Sur-Reply at 2. According to Petitioner, in essence, SMD was a "dummy" corporation created by the government as a part of a sting operation. P. Response at 3. Petitioner states that, even had the June 27th TriSpan letter been sent to SMD, there couldn't have been any inducement of SMD which might have resulted in the submission of a fraudulent Medicare claim.

Petitioner's argument, although interesting, is without merit. The regulations are concise. Petitioner pleaded to a charge of "withholding a material fact for use in determining *rights to benefits and payments under a Federal health care program*." I.G. Ex. 2, at 1 (emphasis added). The specific sections of the United States Code to which Petitioner pleaded guilty provide:

> **(a) Making or causing to be made false statements or representations**
>
> Whoever -
>
> > (2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,. . . .
> >
> > shall
> >
> > (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or

> assistance by any other person, [shall] be guilty of a misdemeanor. . . .

42 U.S.C. §§ 1320a-7b(a)(2), (a)(ii).

Petitioner also executed a sworn Stipulation of Facts which substantiates the charges pleaded to by Petitioner. P. Ex. 3, at 30-31. Convictions under 42 U.S.C. § 1320a-7b(a), with respect to Medicare, are deemed to be program-related within the meaning of section 1128(a)(1) of the Act. Therefore, the criminal information, judgment of conviction, and relevant statutes establish the Petitioner was convicted of an offense that provides a basis for exclusion under section 1128(a)(1) of the Act. *See Lorna Fay Gardner*, DAB No. 1733 (2000).

4. Neither an ALJ nor the I.G. may impose a permissive exclusion once a legal basis for a mandatory exclusion has been established.

Petitioner maintains that the I.G. erred in excluding him under the provisions of section 1128(a)(1) and instead should have exercised his discretion and excluded Petitioner under section 1128(b)(11). Petitioner requests that I change Petitioner's exclusion from mandatory to permissive and impose a penalty consistent with prior section 1128(b)(11) decisions.

The I.G. contends that the regulations provide that, if a party is convicted of a program-related crime, the Secretary is mandated to exclude that party from program participation pursuant to section 1128(a)(1) of the Act. I.G. Br. at 4-5. The I.G. also asserts that Petitioner was convicted of a program-related crime and, thus, Petitioner's exclusion is mandatory under section 1128(a)(1). I.G. Reply at 1-2.

The I.G. additionally contends that Petitioner's exclusion under 1128(a)(1) has a legal basis and, therefore the exclusion must be upheld. *Id.* at 3. Petitioner was convicted of "withholding a document material to the determination regarding whether the right to benefits or payment for Petitioner's product existed under Medicare." *Id.* at 4; I.G. Ex. 3. Thus, the I.G. concludes, the conviction serves as the legal basis for Petitioner's exclusion under section 1128(a)(1) of the Act. *Id.*

Petitioner argues that his conviction is not related to the delivery of an item or services under the Medicare program as delineated under section 1128(a) of the Act. Petitioner contends that the facts of this case support an exclusion pursuant to section 1128(b) of the Act. P. Response at 1-2. Petitioner asserts that his conviction could be the basis of a permissive exclusion under section 1128(b)(1)(A)(i) of the Act, because the plea was for a misdemeanor and not a felony. Petitioner argues that the misdemeanor portion of the United States Code under which he pleaded guilty does not mention a "provision of items or services under federal health care programs," and therefore "falls outside the legal requirements for the imposition of a mandatory exclusion." P. Response at 7.

Petitioner contends that the I.G.'s interpretation of section 1128(a)(1) is overly broad and does not take into consideration both elements of the regulation and "should be

construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant. . . ." P. Response at 7 (*citing Hibbs v. Winn*, 124 S.Ct. 2276, 2286 (2004) (*quoting* 2A N. Singer, *Statutes and Statutory Construction* § 46.06, pp. 181-86 (rev. 6th ed. 2000)).

Petitioner goes on to averthat the conduct for which he pleaded guilty is covered under section 1128(b)(11) of the Act which provides for the exclusion of -

> Any individual or entity furnishing items or services for which payment may be made under title XVIII or a State health care program fails to provide such information as the Secretary or the appropriate State agency finds necessary to determine whether such payments are or were due and the amounts thereof, or has refused to permit such examination of its records by or on behalf of the Secretary or that agency as may be necessary to very such information.

See P. Response at 7-8. Petitioner argues that, in not giving full consideration to the "related to delivery of items or services" language of section 1128(a)(1), and excluding Petitioner under the mandatory provision, makes section 1128(b)(11) of the Act meaningless. *Id*. at 8. Petitioner concludes by opining that a better reading of the provisions of both sections 1128(a)(1) and 1128(b)(11) would be to apply section 1128(a)(1) to felony convictions under sections 1128B(a)(2)(i) and section 1128(b)(11) should be applicable to misdemeanor convictions under section 1128B(a)(2)(ii). *Id.*

Section 1128(a)(1) of the Act requires the Secretary to exclude from participation in any federal health care program, as defined in section 1128B(f) of the Act, any individual convicted of a criminal offense relating to the delivery of a health care item or service. The statute is unambiguous as to the discretionary nature of the provision - the exclusion is mandatory.

Section 1128(b) of the Act is indeed permissive, and it does apply to certain misdemeanor offenses. However, numerous ALJ and appellate decisions of the Departmental Appeals Board have determined that, in matters where a conviction triggers both the mandatory (section 1128(a)) and permissive (section 1128(b)) exclusion provisions, the Secretary does not have discretion as to which provision to impose. The Secretary is required to implement the mandatory exclusion. *See*, *e.g.*, *Touradj Farhadi, M.D.*, DAB CR1072 (2003); *Boris Lipovsky, M.D.*, DAB No. 1363 (1992); *Kenneth M. Behr*, DAB No. 1997 (2005). An appellate panel of the Departmental Appeals Board (the Board), in its rejection of the petitioner's argument in *Lorna Fay Gardner*, DAB No. 1733 (2000), explained that:

> The distinction Congress created between felonies and misdemeanors applied only to nonprogram-related offenses. Since Congress so clearly distinguished between criminal offenses based on whether they were related to Medicare or other State health care programs, we reject Petitioner's contention that the more specific reference to misdemeanor offenses relating to other health care programs should control over the

> general reference to program-related criminal offenses of all degrees as requiring mandatory exclusion under section 1128(a)(1).

Id. at 6.

The crux of Petitioner's argument rests on his contention that he does not meet the requirements relating to the delivery of an item or service under Medicare. I have already concluded that Petitioner was convicted of a program-related crime. Therefore, based upon the circumstances before me, Petitioner's argument is not convincing. On its face, Petitioner's exclusion falls under both the mandatory and permissive exclusion provisions. Thus, for the reasons previously addressed, in such instances the I.G. must exclude a party in accordance with the mandatory exclusion provision.

5. Petitioner's exclusion for a period of five years is the mandatory minimum period as a matter of law.

An exclusion under section 1128(a)(1) of the Act must be for a minimum mandatory period of five years, as set forth in section 1128(c)(3)(B) of the Act:

> Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years. . . .

When the I.G. imposes an exclusion for the mandatory five-year period, the reasonableness of the length of the exclusion is not an issue. 42 C.F.R. § 1001.2007 (a)(2). Aggravating factors that justify lengthening the exclusion period may be taken into consideration, but the five-year period of exclusion will not be shortened. Petitioner was convicted of a criminal offense related to the delivery of an item or service under Medicare. As a result of Petitioner's program-related conviction, the I.G. was required to exclude him for at least five years.

IV. CONCLUSION

Sections 1128(a)(1) and 1128(c)(3)(B) of the Act mandate that Petitioner be excluded from Medicare, Medicaid, and all federal health care programs, for a minimum mandatory period of five years because of his conviction of a criminal offense related to the delivery of an item or service under Medicare. I therefore conclude that the I.G. properly excluded Petitioner from program participation, and I uphold the five-year exclusion.

JUDGE ...TO TOP

Alfonso J. Montano

Administrative Law Judge

FOOTNOTES ...TO TOP

1. Counsel for Petitioner in the present case also represents the petitioner in a related case, *James Randall Benham v. the Inspector General*, Docket No. C-05-373. The issues addressed during the conference call related to both Petitioner in

this case as well as Petitioner in the *Benham* case.

CASE | DECISION | JUDGE | FOOTNOTES

Exhibit D

AUGUSTINE
BIOMEDICAL + DESIGN

Mr. Kurt Hilzinger
Managing Partner
Court Square Capital Partners
Park Avenue Plaza
55 East 52nd St., 34th Floor
New York, NY 10055

July 9, 2010

Dear Mr. Hilzinger,

I read the FDA "Warning Letter" to Arizant with great interest. It must be disconcerting to know that the team protecting your investment cannot comply with the FDA's most basic reporting requirements.

Coincidently, last week an independent anesthesiologist filed a long and detailed MDR complaint about Bair Hugger warming and Arizant to the FDA. A copy of the complaint is enclosed for your review.

Several regulatory issues similar to those about which Arizant was just warned are raised in the complaint. Two key additional patient safety issues were also raised:

1. Bair Hugger blowers are contaminated with germs in their airflow paths; they cannot be cleaned; and they are aerosolizing germs into the operating room air.
2. The waste heat of Bair Hugger warming destroys the protection of both laminar flow and conventional ventilation in the operating room. The waste heat can mobilize contaminated air from the floor and convey it up and into the surgical site.

Your Arizant team may assure you that these issues are not real—that they are merely marketing attacks raised by a competitor. I urge you to look at the enclosed research yourself and I can assure you that there is much more yet to be published. The issues are not simply marketing problems as your team has treated them thus far. Rather, they are patient safety issues that have now graduated to become regulatory matters.

Arizant has no solution to either problem. How can I be so certain?

1. The only reasonable, albeit partial, solution for contaminated blowers is to restore the quality of Bair Huggers' inlet filters and install an outlet filter on the hoses. My company, however, has patents pending on every conceivable variation of hose-end filter. Patent claims should issue this year. Nevertheless, your team has refused to talk to me about acquiring this technology.
2. There is no forced-air solution to the laminar flow disruption issue. Therefore, an air-free warming technology must be substituted in orthopedic and other laminar flow operating rooms. Hot Dog warming is the only FDA- and SCIP-approved, practical air-free warming technology in the US.

6581 City West Parkway, Eden Prairie, MN 55344
Phone (952) 465-3500 **Toll Free** 1-(866) 484-3505
Fax (952) 465-3501 **Web** www.AugustineBiomedical.com

As you see, the solutions to both of Arizant's problems are in my control. Although I am willing to help, I sense that your team's general belief that I am obsessed, crazy and vengeful may be clouding your judgment regarding dealing with me in a business-like manner. Let me assure you: I am not motivated by vengeance. I am just an entrepreneur and this is business. You have problems; I have solutions. That ought to lead us to doing business together.

In the long-term, you are in the classic "Innovators Dilemma" trap. On that battleground, your old technology and our new technology will simply fight it out. Your short-term problem, however, is staying alive should the FDA force a mandatory recall of contaminated Bair Hugger blowers. You currently have at least three separate possibilities for recalls: inlet filters; outlet filters; and contraindication for use in some or all operating rooms (eg orthopedics). I think the odds of a recall for one or more of these issues are significantly greater than 50/50.

If a recall is ordered, Arizant's survival will depend on having a solution ready to be immediately implemented (previously identified, developed, manufactured and 510k cleared). Otherwise, the market share that you lose while fixing the problem will be catastrophic. Considering that you do not have solutions for these problems, your $500 million in shareholder value is one arbitrary and capricious stroke of a regulator's pen away from vaporizing. Unlike legal fights, there is no due process with the FDA, no appeals and little room for negotiation.

I have a proposal that would benefit us both. Let me know if you would like to meet and to discuss the possibilities.

Yours truly,

Scott Augustine MD
CEO

PS: Take a look at this website; http://www.surgicalsiteinfectionattorneys.com. The word has gotten out to the plaintiffs' attorneys: wound infections that occur after Bair Hugger warming are grounds for product liability suits. You should be motivated to fix your product problems for reasons other than just the FDA.

Exhibit E

AUGUSTINE
TEMPERATURE MANAGEMENT

Ms. Debra Rectenwald
President and GM – Infection Prevention Division
3M Health Care Business
3M Center, Building 275-4E-01
St. Paul, MN 55144-1000

June 21, 2010

Re: 3M/Arizant regulatory responsibilities for Bair Hugger®

Dear Ms. Rectenwald,

With your recent acquisition of Arizant/Bair Hugger, you acquired some significant patient-safety and regulatory problems. Presumably, neither you nor your regulatory/legal advisors were fully aware of the problems before the acquisition. Because of 3M's reputation for integrity and interest in protecting patients, however, I am confident that you will not ignore these problems once they have been revealed to you. I urge you to independently confirm the facts contained in this letter. Once the facts are confirmed, your legal and moral obligations will be clear: honestly report the risks, recall Bair Hugger blowers from the field and change labeling to contraindicate their use in orthopedic surgery.

Bair Hugger warming has two serious defects. Arizant is well aware of both. Rather than responsibly reporting and fixing the problems, the company has obfuscated and obscured the issues with marketing rhetoric. The medical device industry has seen other companies cover up known safety problems; the practice always ends in disaster – both for patients and for the company.

I apologize in advance for the length of this letter, but I want to provide sufficient detail for you to take immediate action.

A.) Defect #1: Blower contamination

Since as early as 1997, studies have reported that Bair Hugger blowers were internally contaminated with bacteria which can cause surgical site infections (SSI). For example, see the following:

* Baker N, King D, and Smith EG, "Infection control hazards of intraoperative forced air warming," *The Journal of Hospital Infection* 51, no. 2 (June 2002): 153-4

> Cultured a convective warming unit routinely used in ultra clean orthopedic theaters by swabbing the exterior and interior of the device. Heavy colonization was detected in all samples. Based upon prior research and their own data, Baker et al. recommended against the use of convective warming for orthopedic procedures based upon the elevated risk of SSI.

More recently, other scientists followed-up with three research studies showing that nearly all of the Bair Hugger blowers tested were contaminated with pathogenic germs in their internal airflow paths. Further, the majority of the blowers were depositing massive numbers of internally generated germ-sized particles into the operating rooms. Two of these studies have been published:

> Leaper D et al. "Forced-air warming: a source of airborne contamination in the operating room?" *Orthopedic Reviews* 2009;1:e28;
>
> Albrecht M, Leaper D et al. "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room" *American Journal of Infection Control* 2011; May:321-328 (Attachment 1).
>
> The third study has been submitted for publication.

The *AJIC* article also revealed that sometime in the last 8 years, Arizant "dumbed down" the inlet filter of their blowers from the HEPA filtration (99.97% efficient) that Arizant had pledged to the FDA in their 510k, to 62% efficiency. Arizant's reasons for this change may have been legitimate (perhaps to increase airflow), but the unintended consequence is that nearly all Bair Hugger blowers are now internally contaminated with pathogenic bacteria. They are growing germs in their internal airflow paths, and these airflow paths cannot be accessed for decontamination.

Arizant's response:
Before the *AJIC* article was published, Arizant attempted to pressure lead author David Leaper, threatening that conducting such research would put him in legal and professional jeopardy. In a representation to a German court, Arizant flatly denied the decrease in filtration efficiency. (Please see filtration efficiency report, Attachment 2) Most consistently, Arizant has relied on marketing, proclaiming that "not a single report of a surgical site infection" has been linked to Bair Hugger. (Arizant website: "The Truth About FAW")

The argument is clever because Arizant knows that it is nearly impossible to trace a particular germ to its source. However, while it may confuse customers, it does not address the real issue. Bair Hugger blowers are contaminated with bacteria and cannot be cleaned. The bacteria blow out the hose and into the operating room. Airborne bacterial contamination is known to cause implant infections. You cannot infer that it is a safe practice to blow pathogenic bacteria into the operating room simply because it is nearly impossible to trace a particular bacterium from a wound infection back to a Bair Hugger blower.

Arizant also routinely cites to several underpowered, poorly designed studies—and then draws conclusions that the studies cannot support. The studies—and their defects—include the following:

* Moretti B, Larocca AM, Napoli C., et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection? *J Hospital Infect* 2009; 73: 58–63

Anaylsis: Very small 20 patient study, is totally under-powered to show infection risk. Lack of detail about ventilation flow obstructions makes the relative contamination from upper body warming unpredictable and irrelevant.

* Huang JK, Shah EF, Vinodkumar N, Hegarty MA, Greatorex RA. The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk? *Crit Care* 2003;7:R13–R16.

Analysis: Very small 16 patient study, showed that bacteria are mobilized off of the patient's skin by FAW. As would be expected, the airborne bacteria did not cause any soft tissue infections. Totally irrelevant to orthopedic infection risks.

* Zink RS and Iaizzo PA. Convective warming therapy does not increase the risk of wound contamination in the operating room. Anesth Analg 1993;76(1):50-53

Analysis: Very small 8 subject study, new (uncontaminated) blowers, clean operating room after normal work hours, no surgeon, staff or lights (no ventilation flow obstructions or bacteria generators). Irrelevant to actual surgical conditions.

* Olmsted RN, Kulpmann R, Schlautmann B. Effect of Forced-Air Warming on Operating Theatre Air Quality: assessment using submicron particle release, *Hospital Infection Society*, 2010.

Analysis: This study, although cited by Arizant as proof of safety, apparently does not actually exist. A Google search does not reveal it.

What Arizant should have done:
1. Report the problem to the FDA and to their customers.
2. Recall all of the blowers for cleaning and decontamination.
3. Go back to HEPA filtration on the inlet.
4. Add a HEPA filter on the hose outlet since the internal airflow path of the blowers cannot be periodically decontaminated or cleaned. (Augustine Biomedical + Design has a patent pending on hose outlet filtration for forced-air blowers. We would be happy to sell this technology to 3M.)

B.) Defect #2: OR ventilation disruption and contamination with waste heat

Nearly two years ago, ABD discovered and reported to Arizant that the waste heat from Bair Hugger warming escapes from under the operating table and rises into the OR ventilation. The heat warms contaminated air normally resident near the floor, causing it to also rise into

the sterile surgical field above the surgical table. To see it happen, take a look at these web sites:

http://www.youtube.com/watch?v=BKFl2rINa9g
http://www.heat-rises.blogspot.com

This is very serious and very dangerous for patients. It only takes a single bacterium to infect an orthopedic joint implant (and probably any other implant such as cardiac and neurosurgery) and research has shown that the germ usually gets into the wound by the airborne route. (Whyte W. The role of clothing and drapes in the operating room. J. Hosp. Infect. 1988 May;11 Suppl C:2-17.)

The video evidence cited above has recently been validated by a study that has been peer-reviewed and accepted for publication in a major medical journal -- ("Forced Air Warming and Ultra-Clean Ventilation Do Not Mix: An Investigation of Theatre Ventilation, Patient Warming and Joint Replacement Infection in Orthopedics" – abstract attached 3).

Arizant's response:
Arizant has responded with threats of litigation (see letter from the Dechert law firm, Attachment 4), denial and obfuscation. For example, in an advertisement in the UK's *Theatre Journal* and on the webpages entitled "The Truth About FAW," (created after the 3M acquisition) Arizant has stated:

1. "FAW does not increase the risk of bacterial contamination of operating theatres."

2. FAW can't disrupt laminar flow because a blower "delivers less than one percent of the airflow of a laminar flow system."

3. "[T]here is no disruption of laminar flow tied to the use of forced-air warmers."

4. "Bair Hugger blankets have no significant effect on operating room airflow."

In June 2010 statements to a German court, Arizant represented:

1. Bair Hugger cannot contaminate operating rooms because laminar flow will force any particulates to the ground.

2. Hot air escaping from Bair Hugger blowers will be cooled down instantly by laminar flow and cannot reach the sterile field.

3. Bair Hugger filters air at a minimum of 89% efficiency and averages 93-97% efficiency.

It must be emphasized that these last three statements are not simply clever marketing obfuscations, in fact, they are each willfully false testimony to the German court.

In one of its most disingenuous acts, Arizant hired infection control expert Russ Olmstad (president of APIC, an organization that relies significantly on 3M for financial support), to address the Advisory Committee to Medicare during a webinar in 2010. Olmstad, citing to the research of computational flow dynamics (CFD) colleague Dr. Farhad Memarzadeh, assured the Committee that Bair Hugger warmers could not possibly affect laminar flow

ventilation. As an "expert witness" for Arizant, his apparent objective was to convince the Committee that the CFD modeling is an accurate surrogate of reality. Of course he knew that in order to believe the CFD modeling that he was presenting, you must first ignore reality -- which can be seen at http://www.heat-rises.blogspot.com but was not disclosed to the Committee. Olmstad most certainly knew that while computer modeling can be used to predict reality, it cannot be used to refute reality, especially in "expert" testimony to Medicare.

Such behavior suggests that deceit has become the normal way of doing business at Arizant, that they will do anything to keep the truth from becoming public. For more proof, consider the recent "review" article in the ASA Newsletter by Dr. Daniel Sessler—defending Bair Hugger with non-peer-reviewed research that Arizant paid Dr. Sessler to produce. My Letter to the Editor rebutting Dr. Sessler and its cover letter are attached (Attachments 5,6,7). I've also attached an email that Dr. Sessler sent to me that documents that Arizant has grossly over-paid for his research services over many years. This may explain why he is willing to risk his reputation defending an indefensible position. The fact that 3M is paying influential researchers for influence rather than research is problematic.

Ms. Rectenwald, 3M has an obligation to tell the truth. FDA regulations, the Lanham Act and basic ethics all require that 3M stop dealing with these as marketing problems and responsibly confront them as patient-safety issues. I urge you to actually look at the research we cite; look at the video taken by the orthopedic surgeons in Northumbria. Bair Hugger has real problems. It creates real risks for patients. Finally, the problems cannot be solved by clever marketing.

What Arizant should have done:
1. Notify the FDA and customers of the problem of OR contamination by waste heat from Bair Hugger blowers.
2. Since the problem cannot be fixed, Arizant should have changed its labeling to contraindicate Bair Hugger use during implant surgery – especially orthopedic implant surgery.

C.) Consequences of Bair Hugger's defects

Here is the ultimate fact that 3M must face: **Bair Hugger warming significantly increases deep joint infections.**

Until now, we have never made a statement that links the word "infection" to "Bair Hugger." We have limited our discussion to "contamination," because that was all the research supported. That limitation, however, will not exist much longer.

The previously mentioned study that has been accepted for publication in a major journal ("Forced Air Warming and Ultra-Clean Ventilation Do Not Mix: An Investigation of Theatre Ventilation, Patient Warming and Joint Replacement Infection in Orthopedics" – Attachment 3), includes the following sentence in the abstract:

> **"[Bair Hugger®] Patient warming ventilation disruption was associated with a significant increase in deep joint infections**, as demonstrated by an elevated infection odds-ratio (3.8, p=0.028) for the forced air versus conductive fabric patient groups (n=1437 cases, 2.5-year period)." (emphasis added)

Research results from another hospital, which have also been submitted for publication, show that the deep joint infection rates dropped by 81% after switching from Bair Hugger to HotDog warming. Similar studies are being conducted in numerous other hospitals. We are confident that we will see similar drops in orthopedic deep joint infection rates repeated over and over. We will continue to submit these results for publication in peer-reviewed journals.

Arizant's response:
Not surprisingly, Arizant also threatened the investigators involved with this latest study.

Arizant is unaware that this study has been accepted for publication. As noted above, however, Arizant frequently brags that no surgical site infection has ever been linked to Bair Hugger warming. That claim will soon seem very empty.

Arizant also routinely asks customers to rely on Dr. Sessler's study showing reduced infection rates in colon surgery, suggesting that that data applies to all types of surgery. Such reliance, as Arizant's internal scientists must know, is illogical. There are two fundamentally different mechanisms of causation between soft tissue infections and deep joint (implant) infections. Soft tissue infections require an inoculum of more than 10,000 germs, and the germs are almost always contaminants from the adjacent skin or from cut bowel. In contrast, deep joint infections require only a single germ to cause the infection and that germ is usually delivered to the wound by airborne contamination. (Whyte W. The role of clothing and drapes in the operating room. J. Hosp. Infect. 1988 May;11 Suppl C:2-17. and Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. Am J Infect Control. 1999 Apr;27(2):97-132; quiz 133-134; discussion 96.)

Arizant's claims of universal infection safety (including orthopedic implants) based on Sessler's colon surgery research are simply unfounded, deceptive and, thus, dangerous.

What Arizant should do:
1. Report the infection problem to the FDA and to their customers.
2. Since the problem cannot be fixed, change their labeling to contraindicate Bair Hugger use during implant surgery – especially orthopedic implant surgery.

D.) Product liability exposure:

Arizant seems to feel immune from liability, comfortable because they have never been sued for an OR-acquired SSI. This is a false security. OR-acquired infections clearly occur, but until now it has been impossible for an expert witness to testify as to causation. Therefore, up until now the plaintiffs' lawyers have routinely refused the cases. This is about to change. With the new evidence being published, experts have indicated that they will be able to testify that-- in the absence of a breech of protocol-- there is a greater than 50% probability that an OR-acquired deep joint infection was "caused" by Bair Hugger warming. Imagine the impact that the video from http://www.heat-rises.blogspot.com will have on a jury. Plaintiffs' lawyers are already trolling for Bair Hugger product liability cases. See http://www.stlouisinjurylawblog.com/35 and www.surgicalsiteinfectionattorneys.com.

3M may have a huge product liability exposure. How big is huge? Let's assume that Bair Hugger is shown to increase deep joint infections by only one percentage point (the increase was 2.3% and 1.3% in the two studies to date). If an "average" hospital does about 1000 joint replacements a year, one could attribute 10 deep joint infections per year to Bair Hugger (1% of 1000).

Treatment of these extremely serious complications includes:

1. Take the patient back to surgery to ex-plant the new joint.
2. 4-6 weeks of antibiotics (longer for resistant infections), at least some of which must be done as an inpatient. The patient does not have a joint during this time.
3. If the patient survives the infection and does not require an amputation to control the infection, he or she eventually goes back to surgery to re-implant the joint onto the previously infected bone and hope for the best.

The hard cost for each infection is around $100,000, and that does not include any payment for pain and suffering. Therefore, the 10 infections per year in an "average" hospital would cost $1,000,000 per year. The hospital gets stuck with this bill: Medicare no longer pays for these complications. Patients (or a class of patients) certainly could bring a product liability action against 3M. Perhaps a hospital or even a group of hospitals could pool their infections into a product liability suit. $1 million per year per average hospital adds up petty fast! What would be the added punitive damages – especially considering how 3M/Arizant has actively concealed the truth and failed to report or fix the serious safety problems that were well-known to them? The possible damages are staggering, even for a company the size of 3M.

What effect will the press coverage of a few infection-related product liability suits have on 3M's pristine corporate image and the positioning of the Infection Prevention Division's other products? You may be interested to know that one of your more aggressive competitors has already initiated acquisition discussions and due diligence for the HotDog technology. Obviously, they see HotDog as an opportunity to take the patient warming market from Bair Hugger. However, they also see the negative image of Bair Hugger contamination in the OR adversely affecting your other Infection Prevention products, and they are eager to take advantage of that weakness.

Obviously, I am not threatening when I offer these possibilities. I have no power to make product liability lawsuits suddenly appear. My only point is that 3M must stop pretending that this problem does not exist—and deal with it as I have suggested above.

E.) FDA notification:

I have enclosed an MDR complaint that was filed with the FDA by an outside physician in July of 2010. It's self-explanatory. As far as we know, the FDA has not yet taken action on this complaint. However, the FDA will certainly be updated as new studies publish. Eventually the FDA will have to respond.

This MDR was provided by us to Arizant and Court Square Partners prior to 3M's acquisition of the company. I can only assume that they produced their copy of this document for you during the due diligence process. (Attachment 8)

In summary, 3M bought some really big problems in the Bair Hugger acquisition. Now that you own the product, you have a responsibility to notify the authorities and your customers, fix the problems and/or recall the product from the market and contraindicate for use in ultra-clean surgery such as orthopedics. These are serious regulatory and patient safety problems – the rules clearly dictate that ignoring them is not an option. So far, however, Arizant/3M has treated these serious problems as though they are marketing issues, responding with rhetoric and obfuscation. Patient safety problems in the medical device industry, however, cannot be buried in clever marketing rhetoric.

3M must stop ignoring these problems and begin immediately to take responsible actions to protect patient safety.

Regards,

Scott Augustine MD
CEO
Augustine Temperature Management

Cc: George W. Buckley
President and CEO

Inge G. Thulin
EVP and COO

Brad T. Sauer
EVP, Health Care Business

Marschall I. Smith
SVP, Legal Affairs and General Counsel

Ann Marie Hanrahan
VP, Global Compliance and Business Conduct

Exhibit F

AUGUSTINE
TEMPERATURE MANAGEMENT

January 4, 2012

Debra A. Rectenwald
President, Infection Prevention Division
3M Center Building 0275-04-E-01
St. Paul, MN 55144-1000

Re: Solution to the Bair Hugger waste heat problem

Dear Ms. Rectenwald,

One of these days you are going to realize that 3M has two serious problems with the Bair Hugger franchise that need to be reported both to the FDA and customers, and then fixed. Unfortunately for you, one of the problems – the waste heat issue, cannot be fixed.

A simple denial may be sufficient to convince Eric Wieffering from the Strib but I can assure you that every single orthopedic surgeon that has seen the recent JBJS article, is convinced that Bair Hugger warming is an infection risk during joint replacements. There is not the slightest chance that Bair Hugger warming will survive in orthopedic surgery, it is only a matter of time.

If you loose orthopedics in any given hospital, the odds are that you will loose the rest of the hospital within six months. This is not hypothetical, this is happening already. We just got the purchase commitment from a four-hospital system, driven primarily by the orthopedic risk.

I believe that there is a very high probability that 3M will have to write-off some or all of its $810 million investment in Bair Hugger, over the next couple of years. It is going to seriously hurt when you have to take that $810M out of hiding on the Balance Sheet and move it to the very public "loss" side of the P&L.

Now the good news – HotDog warming is for sale. If 3M owned both warming technologies, you could control the transition of the market from Bair Hugger to HotDog. If we control the transition, it will be an "all or none" situation and there will be a lot of negative marketing rhetoric about 3M causing infections. If you control the transition, you can convert parts of the hospital without converting the whole thing and you can do it quietly. Bair Hugger will still be in use and you will not have lost that customer. In that case, you may not have to even write-off the declining contribution from Bair Hugger.

The idea of spending another half billion dollars to own a patient warming franchise may be a bit painful but at least the whole investment stays on the Balance Sheet. In contrast, when you start writing off the $810M, it is going to be very public and very painful when it hits the P&L.

If a deal like this is at all interesting, you should probably get on with it. Once we are successful in the market, not only will we have many more potential acquirers but the FTC may not allow 3M to own both of the market-leading patient warming technologies.

I am available to informally (or formally) chat about a possible deal if you are interested.

Augustine Temperature Management
6581 City West Parkway
Eden Prairie, MN 55344
U.S.A.

AUGUSTINE
TEMPERATURE MANAGEMENT

Happy New Year!

Regards,

Scott Augustine, MD
CEO
952-465-3502

Cc: Brad T. Sauer
EVP, Health Care Business

Robert Buehler
VP, Patient Warming Business at 3M Infection Prevention Division

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